

PATENT
Atty Docket: 53951-102
Ser. No. 10/650,935

REMARKS

Restriction and Species Election

Claims 1-29 are canceled to comply with the restriction and species election agreed to in teleconference with the Examiner. No traverse is made.

Claim Objections

Objections to claim numbering and various informalities were made in the Office Action. Each has been addressed by amending the claims.

Rejections under 35 USC §112

Claim 30 was rejected as indefinite for failing to point out whether a port is provided on a non-blood side of a dialyzer. Claim 30 is amended to overcome the rejection. As for claims 37 and 409, lack of antecedent basis for "said access line" in claim 37; "said recirculating flow" in claim 38; "said filter" and "said replacement filter container" in claim 40 are overcome by amendment of the respective claims. As for the identified failure of claim 40 to identify a separator between the blood and dialysate sides, claim 40 was amended to indicate that the membrane separates blood and dialysate sides.

Rejections under 35 USC §102

Claims 40, 41, and 43 stand rejected as anticipated by Truitt et al. (US 5,776,345) and Burbank et al (6,582,385). Claims 40, 41, and 43 are canceled by the present amendment rendering the rejection moot.

Rejections under 35 USC §103

Claim 42 stands rejected as obvious over Polaschegg (US 6,280,632). Claim 42 is canceled by the present amendment rendering the rejection moot.

New Claims

Claims 44-47 are added by this amendment. Claim 44 includes at least the limitations, which are similar to claim 30:

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... venous and arterial lines, each connected to said sterile container by releasable connectors configured for connection to a patient access device;

said blood circuit, said non-blood circuit, said non-blood side of said blood filter or dialyzer, and said container being entirely hermetically isolated from an outside of said fluid circuit except by a flow path through a membrane of said filter or dialyzer, permanently connected, and free of releasable connectors such that fluid may be added to an interior of said sterile container only through said membrane, through said venous and arterial lines only after a seal of said releasable connectors is broken;

... said sterile container may be filled by pumping fluid through said membrane without a possibility of touch contamination until a disconnection of said releasable connectors is made to connect said releasable connectors to a patient access.

The quoted limitations are not shown or rendered obvious by the cited art and the claims conform to the elected invention and species. Claim 45 includes at least the limitations:

... said blood circuit including venous and arterial lines being releasably connected to said sterile container by at least one connector that is configured for connection to a patient access device;

said blood circuit, said non-blood circuit, said non-blood side of said blood filter or dialyzer, and said container being entirely hermetically isolated from an outside of said fluid circuit except by a flow path through a membrane of said filter or dialyzer, permanently connected, and free of releasable connectors such that fluid may be added to an interior of said sterile container only through said membrane, through said venous and arterial lines only after a seal of said releasable connectors is broken;

said at least one connector being pre-connected when said fluid circuit is sterilized so that sterile container may be filled by pumping fluid through said membrane ...

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The quoted limitations are not shown or rendered obvious by the cited art and the claims conform to the elected invention and species. Claim 46 is based on the Examiner statement of reasons for allowance which is directed to a dialysis embodiment:

... at least one patient access port connected to the sterile container to define a recirculation path,

a port on a non-blood side of the dialyzer connectable to a source of dialysate;
said recirculating path being entirely hermetically isolated from an outside of the fluid circuit except by a flow path through a membrane of the filter or dialyzer from the non-blood side to the blood side such that dialysate fluid may be added to the sterile container dialyzer membrane and stored therein;

where a flow through the recirculating path may be established without making any connections or disconnections breaking the hermetic seal.

The quoted limitations are not shown or rendered obvious by the cited art and the claims conform to the elected invention and species.

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Please charge or credit Deposit Account No. 16-2500 for all fees as needed.

Respectfully submitted,

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